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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/796,845 | 03/09/2004 | Paul Craig Haldeman | GUID.023C1 | 2425 |
| 51294 | 7590 | 06/05/2006 | | EXAMINER |
| HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425 | | | JAWORSKI, FRANCIS J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3768 | |

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/796,845 | HALDEMAN, PAUL CRAIG |
| | Examiner Jaworski Francis J. | Art Unit 3768 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 3/9/04 IDS.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 - 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 - 20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/9/04
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 4 and 6 – 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims variously of U.S. Patent No. 6704590. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are directed to a guiding catheter in association with a detector for turbulence transition detection purposes, and claims variously the other features associated with piezocrystal, audio, CW Doppler, and axial/lateral measurements and laser Doppler-detection.

Claim 5 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims variously of U.S. Patent No. 6704590 in view of Leavitt et al (US4790323) since the latter would teach that the axial and lateral components of flow variously claimed as detected in the patent could have been compared as taught col. 2 bottom and col. 4 bottom – col. 5 thereof in order to accurately detect the level of turbulence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 4, 6, 8, 11 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macguire et al (US6514249) insofar as Macguire et al is directed to an apparatus and method and guiding catheter system for an ultrasound Doppler-shift based alternative embodiment position sensing mode for pulmonary vein ablation, wherein with reference to col. 7 lines 14 – 22 and col. 42 line 30 – 43 line 64 together with col. 44 lines 50 – 52 teach that part of the velocity sensed by a Doppler-based position-sensing system in attempting to distinguish between a cardiac vessel and cardiac chamber would be due to turbulence, and greater turbulence is expected within a cardiac chamber such as an atrium relative to for example a pulmonary vein, whereupon detection of turbulence changes as reflected in velocity changes would have

been inherently obvious to MacGuire et al in distinguishing atrium from pulmonary vein, and in conjunction with vein balloon inflation tantamount to laminar vein flow inducement characterizable as both lateral i.e. off-center and along the vessel wall and axial meaning par-axial to the vessel axis.

In at least col. 41 upper half it is acknowledged that ultrasound transmit/receive sensors akin to 1420 – 1424 could comprise piezoelectric material.

In cols. 19 and 21 of Macguire et al it is variously noted that their proposed delivery device is multiple lumen and admits of ablation electrode delivery which represents a general sizing likenable to pacing electrode delivery as well.

An audio output of sensed position is provided, see claim 30 end-portion.

Claim 5 is rejected under 35 USC 103(a) as being obvious over Macguire et al in view of Leavitt et al (US4790323) insofar as the latter teaches that it would have been well-known to assess the level of turbulence which Macguire et al indicates increases in the large volume heart chambers versus cardiac vessels during positioning of the ablation device by comparison of axial and lateral flow measurement components.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macguire et al as applied to claim1 above, and further in view of Cottonaro et al (US4920967) insofar as the latter evidences in a Fig. 10 alternative embodiment that it was well known to entertain a laser Doppler and detector pair as an alternative to piezocrystal Doppler detection..

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Claims 9 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macguire et al as applied to claim 1 above, and further in view of Biegeleisen et al (US5022399). It would have been obvious in view of the latter col. 4 lines 25 – 34 to use CW Doppler in the former in order to avoid range specificity limitations, or pulse Doppler for higher clutter immunity where range is well-defined.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj 05/29/06



Francis J. Jaworski
Primary Examiner